

CLAIMS

1. An apparatus for measuring the volume of fluid in a human or animal body cavity using a non-invasive, ultrasound echo technique, comprising:
- 5 a transducer assembly including a plurality of ultrasound transducers mounted thereon for transmitting and receiving a plurality of ultrasound signals into the body cavity at plural angles of incidence and/or from plural spatial locations;
- means for activating the transducers to produce transmitted ultrasound
- 10 signals;
- means for detecting body cavity wall echoes from received ultrasound signals;
- means for determining, from said received signals, a body cavity height H and depth D;
- 15 means for determining a specific measurement configuration corresponding to the body cavity filling degree from the ultrasound signals that intercept the fluid filled body cavity to thereby select an appropriate predetermined correction factor K corresponding to that specific measurement configuration, for optimal calculation of the volume; and
- 20 means for calculating the fluid volume according to the formula $H \times D \times K$.
2. The apparatus of claim 1 adapted for use where the body cavity is a bladder and the volume of fluid measured is a volume of urine.
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3. The apparatus of claim 1 in which the means for activating includes means for transmitting said plurality of ultrasound signals in a selected order.

4. The apparatus of claim 1 in which the means for detecting uses echo travel time and other beam information from the plurality of ultrasound signals.
- 5 5. The apparatus of claim 1 in which the means for determining selects specific ultrasound signals from the plurality of ultrasound signals corresponding to ultrasound beams that have intercepted the fluid filled body cavity.
- 10 6. The apparatus of claim 1 further including display means for instantaneous display of the calculated fluid volume to allow optimisation of transducer positioning by the user.
7. The apparatus of claim 1 in which the means for deriving includes a
15 memory storing a plurality of empirically predetermined correction factors K.
8. The apparatus of claim 1 including five transducers in the array.
- 20 9. The apparatus of claim 8 in which the five transducers are respectively oriented at angles θ_A , θ_B , θ_C , θ_D , θ_E , to an axis orthogonal to the plane of the transducer array, the angles being approximately $\theta_A = -25^\circ$, $\theta_B = 0^\circ$, $\theta_C = +25^\circ$, $\theta_D = +25^\circ$, $\theta_E = +40^\circ$.
- 25 10. The apparatus of claim 1 in which the number of transducers is selected to yield only gross ranges of bladder filling or indicate a clinically important bladder filling level.

11. The apparatus of claim 1 further including means to input patient information, for example gender, weight and age, to select correction factors for use in the volume calculation.
- 5 12. The apparatus of claim 1, provided with internal memory and means to input and store validated volume measurements to optimize correction factors in a "self learning process".
13. The apparatus of claim 1, provided with means to freeze the read-out
10 with a hold/start button.
14. The apparatus of claim 1, where the transducers are positioned in an assembly so that the echo reflecting areas of the walls of the bladder are approximately located in a single cross-sectional sagittal plane.
- 15 15. The apparatus of claim 1 in which the ultrasound transducers are approximately disk-shaped.
16. The apparatus of claim 1, where the electric power can be provided by
20 a battery.
17. The apparatus of claim 1 further including means for indicating correct caudal-cranial positioning of the transducer assembly over a human bladder.
- 25 18. The apparatus of claim 1 in which the transducer assembly is connected with a cable to a housing containing an input device, a processor, a display and a power supply unit.

19. The apparatus of claim 1, where the transducer assembly further includes an ultrasound coupling material covering the transducers for optimal acoustic coupling and patient convenience.

5 20. A method for measuring the volume of fluid in a human or animal body cavity using a non-invasive, ultrasound echo technique, comprising the steps of:

transmitting a plurality of ultrasonic beams into the region of the body containing the cavity at plural angles of incidence and/or from plural spatial
10 locations;

receiving a plurality of ultrasonic signals from the body;

determining, from said received signals, a body cavity height H and depth D;

determining, from the received signals, a specific measurement
15 configuration corresponding to the body cavity filling degree from the ultrasound signals that intercept the fluid filled body cavity to thereby select an appropriate predetermined correction factor K corresponding to that specific measurement configuration, for optimal calculation of the volume; and

20 calculating the fluid volume according to the formula $H \times D \times K$.

21. The method of claim 20 further including the step of displaying the calculated volume on a display device.

25 22. The method of claim 20 further including the step of transmitting the plurality of ultrasonic beams into the body from a transducer array in which a plurality of transducers are arranged with a predetermined spatial location and mounting angle.

23. The method of claim 20 further including the step of acoustically coupling the transducers of the transducer array to the skin of the body being measured using an acoustic coupling material.

5 24 An apparatus for measuring the volume of fluid in a human or animal body cavity using a non-invasive, ultrasound echo technique, comprising:

one or more transducers for transmitting at least one ultrasound beam into the body such that the at least one beam encompasses a substantial portion of the target body cavity, the beam having at least a first frequency;

10 means for receiving ultrasound echo signals from the body cavity and determining a measure of higher harmonic components of the first frequency in the received signals; and

means for determining a volume of fluid in the body cavity from the measured harmonic components.

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25. The apparatus of claim 24 adapted for use where the body cavity is a bladder and the volume of fluid measured is a volume of urine.

26. The apparatus of claim 25 in which the transducer is adapted to
20 transmit a beam of ultrasound sufficient to subtend the entire human bladder.

27. The apparatus of claim 24 further including means for selecting the received ultrasound signals from within one or more predetermined depth ranges and using only those signals for the determination of volume of fluid
25 in the body cavity.

28. The apparatus of claim 24 or claim 26, where the ultrasound transducer is a curved single active piëzo-electric element, shaped to form a sector of a sphere or cone like sound beam.

29. The apparatus of claim 24, where the ultrasound transducer is combined with a lens material so that the combination of transducer and lens create a wide sound beam to approximately encompass the filled bladder.
- 5 30. The apparatus of claim 24, where the transducer is adapted to transmit at a fundamental ultrasound frequency and is adapted to receive the fundamental and higher harmonic signals of the transmitted frequency.
- 10 31. The apparatus of claim 27 further including means for transmitting, at the fundamental frequency, a multiplicity of different pulses to enhance the higher harmonic components in the received signals.
- 15 32. The apparatus of claim 24 further including means for selecting received signals from approximately a selected depth or distance.
33. The apparatus of claim 32 in which the selected depth or distance is beyond the posterior wall of an average filled human bladder.
- 20 34. The apparatus of claim 24 further including means for determining the scattered power of higher harmonics in the received signal and comparing the scattered power with the backscattered power in the fundamental frequency in an algorithm to calculate the urine volume.
- 25 35. The apparatus of claim 24 further including means for using combined pulse sequences at low transmit power and high transmit power to enhance bladder filling measurement and eliminate patient variation due to for instance obesity.

36. The apparatus of claim 24 further including means for using echo data from a depth close to the position of the average anterior bladder wall in determining volume of fluid to limit the effects of variation in the body proximal to the transducer.

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37. The apparatus of claim 24 further including means for varying the transmitted power in subsequent pulse transmissions, such that linear and non-linear echo signals from various depths can be compared to eliminate effects of patient variation.

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38. The apparatus of claim 24 in which the means for determining volume effects a volume calculation using a prior established look up table.

39. The apparatus of claim 24 further including a display adapted to
15 indicate a volume above a predetermined threshold level, the threshold level being determined according to a specified medical application.

40. The apparatus of claim 24 further including a display adapted to
20 indicate filling below a predetermined threshold level, the threshold level being determined according to a specified medical application.

41. The apparatus of claim 24, where the transducer is housed separately and connected to the rest of the apparatus with a flexible cable.

25 42. The apparatus of claim 24, where the transducer comprises a combination of a first acoustic active surface for optimal transmission and reception at the fundamental frequency and second acoustic active surface for optimal reception of the higher harmonic echo signals.

43. The apparatus of claim 24 having a transducer assembly including a plurality of ultrasound transducers mounted thereon for transmitting and receiving a plurality of ultrasound signals into the body cavity at plural angles of incidence and/or from plural spatial locations and for providing a narrow beam direction in the dorsal direction which is used to detect the anterior and posterior bladder wall; this information is used for appropriate selection of the echo depth for proper recording of the higher harmonic echo signal.

10 44. A method for measuring the volume of fluid in a human or animal body cavity using a non-invasive, ultrasound echo technique, comprising the steps of:

positioning a transducer assembly including a plurality of ultrasound transducers mounted thereon for transmitting and receiving a plurality of ultrasound signals into the body cavity at plural angles of incidence and/or from plural spatial locations;

activating the transducers to produce transmitted ultrasound signals;

detecting body cavity wall echoes from received ultrasound signals;

determining, from said received signals, a body cavity height H and a depth D;

determining a specific measurement configuration corresponding to the body cavity filling degree from the ultrasound signals that intercept the fluid filled body cavity and thereby selecting an appropriate predetermined correction factor K corresponding to that specific measurement configuration, for optimal calculation of the volume; and

calculating the fluid volume according to the formula $H \times D \times K$.

45. A method for measuring the volume of fluid in a human or animal body cavity using a non-invasive, ultrasound echo technique, comprising the steps of:

- using one or more transducers to transmit at least one ultrasound
- 5 beam into the body such that the at least one beam encompasses a substantial portion of the target body cavity, the beam having at least a first frequency;
- receiving ultrasound echo signals from the body cavity;
- determining a measure of higher harmonic components of the first frequency in the received signals; and
- 10 determining a volume of fluid in the body cavity from the measured harmonic components.

46. The apparatus of claim 24 in which the at least one beam comprises a plurality of narrow beams such as those conventionally used for ultrasound

15 imaging.

47. Apparatus substantially as described herein with reference to the accompanying drawings.